

**U.S. District Court  
Southern District of New York (Foley Square)  
CIVIL DOCKET FOR CASE #: 1:15-cv-05487-LTS**

Seife v. United States Food and Drug Administration  
Assigned to: Judge Laura Taylor Swain  
Cause: 05:552 Freedom of Information Act

Date Filed: 07/14/2015  
Jury Demand: None  
Nature of Suit: 895 Freedom of  
Information Act  
Jurisdiction: U.S. Government Defendant

**Plaintiff****Charles Seife**

represented by **David Alan Bahr**  
Bahr Law Offices, P.C.  
1035 1/2 Monroe Street  
Eugene, OR 97402  
(541) 556-6439  
Email: [davebahr@mindspring.com](mailto:davebahr@mindspring.com)  
*PRO HAC VICE*  
*ATTORNEY TO BE NOTICED*

V.

**Defendant****United States Food and Drug  
Administration**

represented by **Jean-David Barnea**  
U.S. Attorney's Office, SDNY (Chambers  
Street)  
86 Chambers Street  
New York, NY 10007  
(212) 637-2679  
Fax: (212) 637-2717  
Email: [jean-david.barnea@usdoj.gov](mailto:jean-david.barnea@usdoj.gov)  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

Date Filed	#	Docket Text
07/14/2015	<u>1</u>	<b>FILING ERROR – DEFICIENT PLEADING – FILED AGAINST PARTY</b> <b>ERROR</b> COMPLAINT against Charles Seife. (Filing Fee \$ 400.00, Receipt Number 0208-11152567) Document filed by Charles Seife.(Bahr, David) Modified on 7/15/2015 (dgo). (Entered: 07/14/2015)
07/14/2015	<u>2</u>	<b>FILING ERROR – DEFICIENT PLEADING – SIGNATURE ERROR – CIVIL</b> COVER SHEET filed. (Bahr, David) Modified on 7/15/2015 (dgo). (Entered: 07/14/2015)
07/14/2015	<u>3</u>	REQUEST FOR ISSUANCE OF SUMMONS as to United States Food and Drug Administration, re: <u>1</u> Complaint. Document filed by Charles Seife. (Bahr, David) (Entered: 07/14/2015)
07/14/2015	<u>4</u>	<b>FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION</b> for David A. Bahr to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208-11152818. <b>Motion and supporting papers to be reviewed by Clerk's Office staff.</b> Document filed by Charles Seife. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing, # <u>2</u> Text of Proposed Order)(Bahr, David) Modified on 7/15/2015 (sdi). (Entered: 07/14/2015)
07/15/2015		>>> <b>NOTICE REGARDING DEFICIENT MOTION TO APPEAR PRO HAC VICE.</b> Notice to RE-FILE Document No. <u>4</u> MOTION for David A. Bahr to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208-11152818. <b>Motion and supporting papers to be reviewed by Clerk's Office staff... The filing is deficient for the following reason(s): missing Certificate of Good Standing from</b>

		Supreme Court of Oregon;; Re–file the motion as a Corrected Motion to Appear Pro Hac Vice – attach the correct signed PDF – select the correct named filer/filers – attach valid Certificates of Good Standing issued within the past 30 days – attach Proposed Order.. (sdi) (Entered: 07/15/2015)
07/15/2015		***NOTICE TO ATTORNEY REGARDING DEFICIENT PLEADING. Notice to Attorney David Alan Bahr to RE–FILE Document No. <u>1</u> Complaint. The filing is deficient for the following reason(s): the wrong party/parties whom the pleading is against were selected;. Re–file the pleading using the event type Complaint found under the event list Complaints and Other Initiating Documents – attach the correct signed PDF – select the individually named filer/filers – select the individually named party/parties the pleading is against. (dgo) (Entered: 07/15/2015)
07/15/2015		***NOTICE TO ATTORNEY REGARDING DEFICIENT CIVIL COVER SHEET. Notice to attorney David Alan Bahr to RE–FILE Document No. <u>2</u> Civil Cover Sheet. The filing is deficient for the following reason(s): No signature;. Re–file the document using the event type Civil Cover Sheet found under the event list Other Documents and attach the correct PDF. (dgo) (Entered: 07/15/2015)
07/15/2015		***NOTICE TO ATTORNEY REGARDING CASE OPENING STATISTICAL ERROR CORRECTION: Notice to attorney David Alan Bahr. The following case opening statistical information was erroneously selected/entered: Arbitration code e (Exempt); Fee Status code due (due);. The following correction(s) have been made to your case entry: the Arbitration code has been deleted; the Fee Status code has been modified to pd (paid);. (dgo) (Entered: 07/15/2015)
07/15/2015		CASE OPENING INITIAL ASSIGNMENT NOTICE: The above–entitled action is assigned to Judge Laura Taylor Swain. Please download and review the Individual Practices of the assigned District Judge, located at <a href="http://nysd.uscourts.gov/judges/District">http://nysd.uscourts.gov/judges/District</a> . Attorneys are responsible for providing courtesy copies to judges where their Individual Practices require such. Please download and review the ECF Rules and Instructions, located at <a href="http://nysd.uscourts.gov/ecf_filing.php">http://nysd.uscourts.gov/ecf_filing.php</a> . (dgo) (Entered: 07/15/2015)
07/15/2015		Magistrate Judge Ronald L. Ellis is so designated. (dgo) (Entered: 07/15/2015)
07/15/2015		Case Designated ECF. (dgo) (Entered: 07/15/2015)
07/15/2015	<u>5</u>	CIVIL COVER SHEET filed. (Bahr, David) (Entered: 07/15/2015)
07/15/2015	<u>6</u>	COMPLAINT against United States Food and Drug Administration. Document filed by Charles Seife.(Bahr, David) (Entered: 07/15/2015)
07/24/2015	<u>7</u>	MOTION for David A. Bahr to Appear Pro Hac Vice ( <i>Corrected</i> ). <b>Motion and supporting papers to be reviewed by Clerk's Office staff.</b> Document filed by Charles Seife. (Attachments: # <u>1</u> Exhibit Certificate of Good Standing from Oregon Supreme Court, # <u>2</u> Text of Proposed Order Proposed Order)(Bahr, David) (Entered: 07/24/2015)
07/27/2015		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. <u>7</u> MOTION for David A. Bahr to Appear Pro Hac Vice ( <i>Corrected</i> ). Motion and supporting papers to be reviewed by Clerk's Office staff.. The document has been reviewed and there are no deficiencies. (bcu) (Entered: 07/27/2015)
08/05/2015	<u>8</u>	INITIAL CONFERENCE ORDER: Initial Conference set for 10/23/2015 at 12:00 PM in Courtroom 12D, 500 Pearl Street, New York, NY 10007 before Judge Laura Taylor Swain. (See Order.) (Signed by Judge Laura Taylor Swain on 8/5/2015) (ajs) (Entered: 08/05/2015)
08/05/2015	<u>9</u>	ORDER FOR ADMISSION PRO HAC VICE granting <u>7</u> Motion for David A. Bahr to Appear Pro Hac Vice. DE # <u>7</u> resolved. (Signed by Judge Laura Taylor Swain on 8/5/2015) (ajs) (Entered: 08/05/2015)
08/05/2015	<u>10</u>	ELECTRONIC SUMMONS ISSUED as to United States Food and Drug Administration. (dgo) (Entered: 08/05/2015)

08/24/2015	<u>11</u>	NOTICE OF APPEARANCE by Jean-David Barnea on behalf of United States Food and Drug Administration. (Barnea, Jean-David) (Entered: 08/24/2015)
08/26/2015	<u>12</u>	LETTER MOTION for Extension of Time to File Answer and <i>Other Relief</i> addressed to Judge Laura Taylor Swain from AUSA Jean-David Barnea dated 8/26/15. Document filed by United States Food and Drug Administration.(Barnea, Jean-David) (Entered: 08/26/2015)
08/31/2015	<u>13</u>	ORDER granting <u>12</u> Letter Motion for Extension of Time to Answer re <u>6</u> Complaint, and Other Relief. The request for extension of time to respond is granted. The request for permission for Plaintiff's counsel to appear telephonically is granted. Plaintiff's counsel must contact the Courtroom Deputy (212 805 0424) by October 21, 2015 for call-in instructions. The request for permission to forego discovery scheduling proposals in the pre-conference submission is granted. The submission must nonetheless address jurisdiction, basis of claims and defenses, disputed and undisputed legal and factual issues, prospects for consensual resolution, consent to transfer to magistrate judge and all other such relevant matters. DE # 12 resolved. United States Food and Drug Administration answer due 10/13/2015. (Signed by Judge Laura Taylor Swain on 8/31/2015) (kko) (Entered: 08/31/2015)
10/13/2015	<u>14</u>	ANSWER to <u>6</u> Complaint. Document filed by United States Food and Drug Administration.(Barnea, Jean-David) (Entered: 10/13/2015)
10/16/2015	<u>15</u>	INITIAL REPORT OF PARTIES BEFORE PRETRIAL CONFERENCE. Document filed by United States Food and Drug Administration.(Barnea, Jean-David) (Entered: 10/16/2015)
10/23/2015		Minute Entry for proceedings held before Judge Laura Taylor Swain: Initial Pretrial Conference held on 10/23/2015. IPTC held and adj to 1/29/2016 at 10:15am. Case is placed on the suspense calendar until further notice. Parties are to submit a status report to the Court by 1/29/2016 as to a settlement, the continuation of the case on suspense or removing the case from suspense. The status report will be due every March 1, June 1, September 1 and January 1. ( Initial Conference set for 1/29/2016 at 10:15 AM in Courtroom 12D, 500 Pearl Street, New York, NY 10007 before Judge Laura Taylor Swain.) (lan) (Entered: 10/23/2015)
10/30/2015	<u>16</u>	STIPULATION AND ORDER REGARDING DOCUMENT SEARCHES AND PRODUCTION: It is hereby STIPULATED and AGREED between the Parties and ORDERED by the Court as follows: 1. Other than as provided herein, all claims are resolved except for those relating to the adequacy of FDA's searches, the propriety of FDA's withholdings, and compliance with this Stipulation. 2. FDA will make monthly productions to Plaintiff in response to the Requests, beginning no later than November 30, 2015, until it completes its response to all Requests. 9. Nothing in this Stipulation and Order, including the fact of its entry, should be taken as a concession by FDA that Plaintiff has "substantially prevailed" in this action in whole or in part, as that term is used in 5 U.S.C. § 552(a)(4)(E). 10. The Clerk of the Court is directed to place this case on the suspense docket. 11. The status conference scheduled for January 29, 2016, at 10:15 a.m. is hereby adjourned sine die. 12. The Parties shall submit joint status reports to the Court every three months beginning March 1, 2016, by letter filed on ECF, in which they will inform the Court of the status of FDA's productions pursuant to this Stipulation and Order, and indicate their views on whether the case should continue to remain on the suspense docket, restored to the active docket of the Court, or dismissed. (As further set forth in this Order.) (Signed by Judge Laura Taylor Swain on 10/29/2015) (spo) (Entered: 10/30/2015)
03/01/2016	<u>17</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean-David Barnea dated 3/1/16 re: Status Update. Document filed by United States Food and Drug Administration.(Barnea, Jean-David) (Entered: 03/01/2016)
03/02/2016	<u>18</u>	MEMO ENDORSEMENT on re: <u>17</u> Letter re: Status Update, filed by United States Food and Drug Administration. ENDORSEMENT: The case will remain on suspense pending the next timely status report. (Signed by Judge Laura Taylor Swain on 3/1/2016) (spo) (Entered: 03/02/2016)
06/01/2016	<u>19</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean-David Barnea dated 6/1/16 re: Status Report re FDA Productions. Document filed by United States Food and Drug Administration.(Barnea, Jean-David) (Entered: 06/01/2016)

06/02/2016	<u>20</u>	MEMO ENDORSEMENT on re: <u>19</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The case will remain on the suspense docket pending the next timely report. (Signed by Judge Laura Taylor Swain on 6/2/2016) (tn) (Entered: 06/02/2016)
08/31/2016	<u>21</u>	LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 8/31/16 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 08/31/2016)
09/07/2016	<u>22</u>	MEMO ENDORSEMENT on re: <u>21</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: SO ORDERED. (Signed by Judge Laura Taylor Swain on 9/6/2016) (cf) (Entered: 09/07/2016)
12/01/2016	<u>23</u>	LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 12/1/16 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 12/01/2016)
12/05/2016	<u>24</u>	MEMO ENDORSEMENT on re: <u>23</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The case will remain on suspense pending the next timely status report. SO ORDERED. (Signed by Judge Laura Taylor Swain on 12/02/2016) (ama) (Entered: 12/05/2016)
02/09/2017	<u>25</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 2/9/17 re: February 2017 Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 02/09/2017)
02/10/2017	<u>26</u>	MEMO ENDORSEMENT on re: <u>25</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The case will remain on the suspense docket pending the next timely report. (Signed by Judge Laura Taylor Swain on 2/10/2017) (cf) (Entered: 02/10/2017)
05/01/2017	<u>27</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 5/1/17 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 05/01/2017)
05/02/2017	<u>28</u>	MEMO ENDORSEMENT: on re: <u>27</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The case will remain on suspense pending the next timely status report. (Signed by Judge Laura Taylor Swain on 5/2/2017) (ap) (Entered: 05/02/2017)
08/01/2017	<u>29</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 8/1/17 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 08/01/2017)
08/03/2017	<u>30</u>	MEMO ENDORSEMENT on re: <u>29</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: SO ORDERED. (Signed by Judge Laura Taylor Swain on 8/3/2017) (cf) (Entered: 08/03/2017)
10/31/2017	<u>31</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 10/31/17 re: Case Status. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 10/31/2017)
11/02/2017	<u>32</u>	MEMO ENDORSEMENT: on re: <u>31</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The Clerk of Court is requested to restore this case to the active docket. The parties must file a status report by December 15, 2017. DE #31 resolved. (Signed by Judge Laura Taylor Swain on 11/1/2017) (ap) (Entered: 11/02/2017)
12/14/2017	<u>33</u>	STATUS REPORT. <i>on behalf of both parties</i> Document filed by Charles Seife.(Bahr, David) (Entered: 12/14/2017)
12/20/2017	<u>34</u>	MEMO ENDORSEMENT: on re: <u>33</u> Status Report filed by Charles Seife. ENDORSEMENT: The requested extension of time for submission of a status report is Granted. DE # 33 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 12/20/2017) (ama) (Entered: 12/20/2017)
01/29/2018	<u>35</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 1/29/18 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 01/29/2018)

01/30/2018	<u>36</u>	MEMO ENDORSEMENT: on re: <u>35</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: A further status report must be filed by March 15, 2018. SO ORDERED. (Signed by Judge Laura Taylor Swain on 1/30/2018) (ama) (Entered: 01/30/2018)
03/13/2018	<u>37</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 3/13/18 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 03/13/2018)
03/14/2018	<u>38</u>	MEMO ENDORSEMENT: on re: <u>37</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The parties must provide a further status report by April 30, 2018. De #37 resolved. (Signed by Judge Laura Taylor Swain on 3/14/2018) (ap) (Entered: 03/14/2018)
04/30/2018	<u>39</u>	STATUS REPORT. <i>on behalf of both parties</i> Document filed by Charles Seife.(Bahr, David) (Entered: 04/30/2018)
05/03/2018	<u>40</u>	MEMO ENDORSEMENT: on re: <u>39</u> Status Report filed by Charles Seife. ENDORSEMENT: The parties must file the next status report by June 14, 2018. SO ORDERED. (Signed by Judge Laura Taylor Swain on 5/03/2018) (ama) (Entered: 05/03/2018)
06/13/2018	<u>41</u>	STATUS REPORT. <i>Joint Case Status Report</i> Document filed by Charles Seife.(Bahr, David) (Entered: 06/13/2018)
06/19/2018	<u>42</u>	MEMO ENDORSEMENT: on re: <u>41</u> Status Report filed by Charles Seife. ENDORSEMENT: The requested extension is Granted. DE # 41 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 6/18/2018) (ama) (Entered: 06/19/2018)
07/27/2018	<u>43</u>	STATUS REPORT. <i>Joint Case Status Report</i> Document filed by Charles Seife.(Bahr, David) (Entered: 07/27/2018)
07/30/2018	<u>44</u>	MEMO ENDORSEMENT on re: <u>43</u> Status Report filed by Charles Seife. ENDORSEMENT: The request is granted. (Signed by Judge Laura Taylor Swain on 7/30/2018) (rj) (Entered: 07/30/2018)
09/13/2018	<u>45</u>	LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 9/13/18 re: Status Report. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 09/13/2018)
09/18/2018	<u>46</u>	MEMO ENDORSEMENT: on re: <u>45</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The next status report must be filed by November 30, 2018. DE # 45 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 9/17/2018) (ama) (Entered: 09/18/2018)
11/30/2018	<u>47</u>	LETTER addressed to Judge Laura Taylor Swain from David Bahr dated 11/30/18 re: Status Report. Document filed by Charles Seife.(Bahr, David) (Entered: 11/30/2018)
12/03/2018	<u>48</u>	MEMO ENDORSEMENT: on re: <u>47</u> Letter filed by Charles Seife. ENDORSEMENT: The requested extension is Granted. The Court extends its condolences. DE # 47. SO ORDERED. (Signed by Judge Laura Taylor Swain on 12/03/2018) (ama) (Entered: 12/03/2018)
12/21/2018	<u>49</u>	LETTER addressed to Judge Laura Taylor Swain from David Bahr dated 12/21/18 re: Joint Case Status Report. Document filed by Charles Seife.(Bahr, David) (Entered: 12/21/2018)
12/26/2018	<u>50</u>	MEMO ENDORSEMENT: on re: <u>49</u> Letter filed by Charles Seife. ENDORSEMENT: The request is Granted, with thanks for the holiday wishes and the same in return. DE # 49 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 12/26/2018) (ama) (Entered: 12/26/2018)
12/27/2018	<u>51</u>	STANDING ORDER M10–468: The United States Attorney's Office shall notify the Court immediately upon the restoration of Department of Justice funding. (As further set forth in this Order.) (Signed by Judge Colleen McMahon on 12/27/2018) (anc) (Entered: 01/02/2019)

12/27/2018		Case Stayed. (anc) (Entered: 01/14/2019)
02/19/2019	<u>52</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 2/19/19 re: Tolling of Case Deadlines. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 02/19/2019)
02/25/2019	<u>53</u>	MEMO ENDORSEMENT on re: <u>52</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The deadline is March 15, 2019. SO ORDERED. (Signed by Judge Laura Taylor Swain on 2/25/2019) (anc) (Entered: 02/25/2019)
03/14/2019	<u>54</u>	LETTER addressed to Judge Laura Taylor Swain from David Bahr dated 3/14/19 re: Joint Case Status Report. Document filed by Charles Seife.(Bahr, David) (Entered: 03/15/2019)
03/15/2019	<u>55</u>	MEMO ENDORSEMENT: on re: <u>54</u> Letter filed by Charles Seife. ENDORSEMENT: The request is Granted. SO ORDERED. (Signed by Judge Laura Taylor Swain on 3/15/2019) (ama) (Entered: 03/15/2019)
04/24/2019	<u>56</u>	STATUS REPORT. <i>Joint Case Status Report</i> Document filed by Charles Seife.(Bahr, David) (Entered: 04/24/2019)
04/26/2019	<u>57</u>	MEMO ENDORSEMENT on re: <u>56</u> Status Report filed by Charles Seife. ENDORSEMENT: The request is granted. The next status report must be filed by May 30, 2019. DE #56 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 4/26/2019) (kv) (Entered: 04/26/2019)
05/30/2019	<u>58</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 5/30/19 re: Status Report and Proposed Briefing Schedule. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 05/30/2019)
05/31/2019	<u>59</u>	MEMO ENDORSEMENT: on re: <u>58</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The request for approval is Denied, without prejudice to submission of a revised schedule under which briefing commences after September 1, 2019. DE # 58 resolved. SO ORDERED. (Signed by Judge Laura Taylor Swain on 5/30/2019) (ama) (Entered: 05/31/2019)
06/05/2019	<u>60</u>	JOINT LETTER addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 6/5/19 re: Revised Proposed Briefing Schedule. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 06/05/2019)
06/11/2019	<u>61</u>	MEMO ENDORSEMENT: on re: <u>60</u> Letter filed by United States Food and Drug Administration. ENDORSEMENT: The proposed schedule is approved. DE # 60 resolved. SO ORDERED., ( Cross Motions due by 10/21/2019., Motions due by 9/6/2019., Responses due by 11/20/2019, Replies due by 12/16/2019.) (Signed by Judge Laura Taylor Swain on 6/07/2019) (ama) (Entered: 06/11/2019)
08/07/2019	<u>62</u>	JOINT LETTER MOTION for Extension of Time for SJ Briefing addressed to Judge Laura Taylor Swain from AUSA Jean–David Barnea dated 8/7/19. Document filed by United States Food and Drug Administration.(Barnea, Jean–David) (Entered: 08/07/2019)